

इंटरनेट

मानक

Disclosure to Promote the Right To Information

Whereas the Parliament of India has set out to provide a practical regime of right to information for citizens to secure access to information under the control of public authorities, in order to promote transparency and accountability in the working of every public authority, and whereas the attached publication of the Bureau of Indian Standards is of particular interest to the public, particularly disadvantaged communities and those engaged in the pursuit of education and knowledge, the attached public safety standard is made available to promote the timely dissemination of this information in an accurate manner to the public.

“जानने का अधिकार, जीने का अधिकार”

Mazdoor Kisan Shakti Sangathan

“The Right to Information, The Right to Live”

“पुराने को छोड़ नये के तरफ”

Jawaharlal Nehru

“Step Out From the Old to the New”

IS 5347-4 (1996): Requirements for orthopaedic implants,
Part 4: Wrought titanium 6-aluminium 4- vanadium alloy [MHD
2: Orthopaedic Instruments, Implants and Accessories]



“ज्ञान से एक नये भारत का निर्माण”

Satyanarayan Gangaram Pitroda

“Invent a New India Using Knowledge”



“ज्ञान एक ऐसा खजाना है जो कभी चुराया नहीं जा सकता है”

Bhartrhari—Nitiśatakam

“Knowledge is such a treasure which cannot be stolen”

BLANK PAGE



भारतीय मानक

अस्थि अन्तर्रोपणो की अपेक्षाएँ

भाग 4 पिटवाँ टाइटेनियम 6-एल्युमिनियम 4-वेनेडियम मिश्रतु

(पहला पुनरीक्षण)

Indian Standard

REQUIREMENTS FOR ORTHOPAEDIC IMPLANTS

PART 4 WROUGHT TITANIUM 6-ALUMINIUM 4-VANADIUM ALLOY

(*First Revision*)

ICS 11.040.40

© BIS 1996

BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

FOREWORD

This Indian Standard (Part 4) (First Revision) which is identical with ISO 5832-3 : 1990 'Implants for surgery — Metallic materials — Part 3 : Wrought titanium 6-aluminium 4-vanadium alloy', issued by the International Organization for Standardization (ISO), was adopted by the Bureau of Indian Standards, on the recommendations of Orthopaedic Instruments and Accessories Sectional Committee and approval of Medical Equipment and Hospital Planning Division Council.

This standard was first published in 1984 as dual number standard. Its first revision has been done to incorporate the modification effected in the second edition of ISO 5832-3 brought out in 1990. In this revised version chemical composition of various elements in the material has been altered. Microstructure examination has been redefined. Reference standards for test methods for mechanical properties that is tensile strength, proof stress, percentage elongation, etc, have been changed from ASTM to ISO Standards.

The text of above mentioned ISO standard has been approved as suitable for publication as Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

- a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.
- b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their place are listed below along with their degree of equivalence for editions indicated:

<i>International Standard</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
ISO 6892 : 1984	IS 1608 : 1972 Method for tensile testing of steel products (<i>first revision</i>)	Technically equivalent

This Indian Standard has been issued in twelve parts. Other parts of this Indian Standard are as follows:

- | | |
|---------|--|
| Part 1 | General requirements |
| Part 2 | Wrought stainless steel |
| Part 3 | Unalloyed titanium |
| Part 5 | Cobalt-chromium-molybdenum casting alloy |
| Part 6 | Wrought-cobalt-chromium tungsten-nickel alloy |
| Part 7 | Wrought cobalt-nickel chromium-molybdenum alloy |
| Part 8 | Forgeable and cold-formed-cobalt-chromium-nickel-molybdenum-iron alloy |
| Part 9 | Ceramic materials based on alumina |
| Part 10 | Ultra-high molecular weight polyethylene, powder form |
| Part 11 | Ultra-high molecular weight polyethylene, moulded form |
| Part 12 | Wrought cobalt-nickel-chromium molybdenum tungsten iron alloy |

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of specified value in this standard.

Indian Standard

REQUIREMENTS FOR ORTHOPAEDIC IMPLANTS

PART 4 WROUGHT TITANIUM 6-ALUMINIUM 4-VANADIUM ALLOY

(First Revision)

1 Scope

This part of ISO 5832 specifies the characteristics of, and corresponding test methods for, the wrought titanium alloy known as titanium 6-aluminium 4-vanadium alloy (Ti 6-Al 4-V alloy) for use in the manufacture of surgical implants.

NOTE 1 The mechanical properties of a sample obtained from a finished product made of this alloy may not necessarily comply with those specified in this part of ISO 5832.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 5832. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 5832 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 6892:1984, *Metallic materials — Tensile testing*.

Publication ETTTC 2, *Microstructural standards for α + β titanium alloy bars*, 1979, the European Titanium Producers Technical Committee (ETTC).¹⁾

3 Chemical composition

The heat analysis of the alloy when tested as specified in clause 6 shall comply with the chemical composition specified in table 1.

Table 1 — Chemical composition

Element	Composition limits % (m/m)
Aluminium	5,5 to 6,75
Vanadium	3,5 to 4,5
Iron	0,3 max.
Oxygen	0,2 max.
Carbon	0,08 max.
Nitrogen	0,05 max.
Hydrogen	0,015 max. ¹⁾
Titanium	Balance

1) Except for billets, for which the maximum hydrogen content shall be 0,01 % (m/m).

4 Microstructure

The microstructure, when examined as indicated in table 3, shall be α + β globular, and shall correspond to photomicrographs A1 to A9 in Publication ETTTC 2 for annealed material. The alloy shall be free of optically visible inclusions at magnification $\times 200$.

5 Mechanical properties

5.1 Test pieces

Representative test pieces for the determination of mechanical properties shall be prepared in accordance with the provisions of ISO 6892.

1) Available from IMI Titanium Ltd., Technical Services Department, P.O. Box 704, Witton, Birmingham B6 7UR, United Kingdom. (This reference will be replaced by reference to an appropriate International Standard when available.)

5.2 Tensile test

The tensile properties of the alloy, determined as specified in clause 6, shall be in accordance with the requirements of table 2.

Should any of the test pieces not meet the specified requirements, or should they break outside the gauge limits, two further test pieces representative of the same batch shall be tested in the same manner. The alloy shall be deemed to comply only if both additional test pieces meet the specified requirements.

If any of the retests fails to meet the appropriate requirements, the product represented shall be deemed not to comply with this part of ISO 5832.

However, the manufacturer may, if he so desires, re-heat-treat the material and resubmit it for testing in accordance with the requirements of this part of ISO 5832.

5.3 Bend test

Titanium alloy sheet or strip, when tested as specified in clause 6, shall not show any cracking on the outside surface of the test pieces.

6 Test methods

The test methods to be used in determining compliance with the requirements of this part of ISO 5832 shall be those given in table 3.

Table 2 — Mechanical properties of alloy in annealed condition

Form of alloy	Ultimate tensile strength min. MPa	Yield strength (0,2 % offset) min. MPa	Elongation ¹⁾ min. %	Reduction of area min. %	Mandrel diameter for bend test ²⁾
Sheet and strip	860	780	8	Not applicable	10 <i>t</i>
Bar ³⁾	860	780	10	25	Not applicable

1) Gauge length = $5,65\sqrt{S_0}$ or 50 mm, where S_0 is the original cross-sectional area in square millimetres.
2) *t* = thickness of the sheet or strip.
3) Maximum diameter or thickness = 75 mm.

Table 3 — Test methods

Requirements	Relevant clause	Test method
Chemical composition	3	Recognized analytical procedures (ISO methods where these exist)
Microstructure	4	ETTC 2
Mechanical properties Ultimate tensile strength Yield strength Elongation Reduction of area Bend test	5	ISO 6892 ISO 6892 ISO 6892 ISO 6892 Bend the sheet or strip around a mandrel of the diameter specified in table 2.

Bureau of Indian Standards

BIS is a statutory institution established under the *Bureau of Indian Standards Act, 1986* to promote harmonious development of the activities of standardization, marking and quality certification of goods and attending to connected matters in the country.

Copyright

BIS has the copyright of all its publications. No part of these publications may be reproduced in any form without the prior permission in writing of BIS. This does not preclude the free use, in the course of implementing the standard, of necessary details, such as symbols and sizes, type or grade designations. Enquiries relating to copyright be addressed to the Director (Publications), BIS.

Review of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Handbook' and 'Standards Monthly Additions'.

This Indian Standard has been developed from Doc : No. MHD 2 (2629).

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

BUREAU OF INDIAN STANDARDS

Headquarters:

Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi 110002
Telephones : 323 01 31, 323 83 75, 323 94 02

Telegrams : Manaksanstha
(Common to all offices)

Regional Offices :

Telephone

Central : Manak Bhavan, 9 Bahadur Shah Zafar Marg ·
NEW DELHI 110002

{ 323 76 17
323 48 41

Eastern : 1/14 C. I.T. Scheme VII M, V. I. P. Road, Maniktola
CALCUTTA 700054

{ 37 84 99, 37 85 61
37 86 26, 37 91 20

Northern : SCO 335-336, Sector 34-A, CHANDIGARH 160022

{ 60 38 43
60 20 25

Southern : C. I. T. Campus, IV Cross Road, MADRAS 600113

{ 235 02 16, 235 04 42
235 15 19, 235 23 15

Western : Manakalaya, E9 MIDC, Marol, Andheri (East)
BOMBAY 400093

{ 832 92 95, 832 78 58
832 78 91, 832 78 92

Branches : AHMADABAD. BANGALORE. BHOPAL. BHUBANESHWAR.
COIMBATORE. FARIDABAD. GHAZIABAD. GUWAHATI. HYDERABAD.
JAIPUR. KANPUR. LUCKNOW. PATNA. THIRUVANANTHAPURAM.